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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,329	08/01/2003	Paul V. Goode JR.	DEXCOM.026A	4198
20995 7590 07/30/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER NASSER, ROBERT L	
			ART UNIT 3735	PAPER NUMBER
			NOTIFICATION DATE 07/30/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/633,329

Applicant(s)

GOODE ET AL.

Examiner

Robert L. Nasser

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14, 17-31, 33, 36-48, 50, 52 and 55-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 14, 17-31, 33, 36-48, 50, 52, and 55-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 3735

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58, 60, 63-72 and 83-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims say that no more than two data points are used for a day, meaning a range of 1-2. The specification only provides support for 1-6 and provides no support for limiting the number to 2. Therefore, the amendment introduces new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7, 15-20, 23-26, 30, 34-40, 43-45, 55-57, 59, 61, 73, 74, 78, 81, 82, 96, 99, and 100, are rejected under 35 U.S.C. 102(b) as being anticipated by the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System," which was cited by applicant. Mastrototaro teaches a method of calibrating a subcutaneously implanted glucose sensor by taking one or more readings from a self monitoring reference sensor and one or more readings from the continuous implanted

sensor, matching the readings to each other, forming a calibration set including at least one matched pair, evaluating the quality of calibration using a data association function (i.e. either mean calculating a calibration or correlation between the sensor and reference readings), converts the sensor data into calibrated data using the a conversion function, and provides data to a display only if the data association function is above a threshold 0.79. In addition, if the quality is not sufficient, the method notifies the user by providing an indication or alarm on the monitor. In addition, Mastrototaro provides trend information. The Mastrototaro article also has a system and a computer system for performing the method. With respect to claims 59 and 78, Mastrototaro uses at three or more matched data pair. With respect to claims 73 and 74, Mastrototaro uses statistical analysis which is a form of evaluating the clinical acceptability of the data. Claims 81 and 82 are rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 8-10, 21, 22, 27-29, 41, 42, 46-48, 79, 80, 97, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrototaro. Claims 2, 3, 21, 22, 41, 42, 79, 80, 97, and 98 are rejected in that the examiner takes official notice that it is well known to smooth data, to eliminate the effects of anomalous data. As such, it would have been obvious to modify Mastrototaro to smooth the data, to improve the accuracy of measurements. Claims 8-10, 27-29, and 46-48 are rejected in that

Mastrototaro does not teach how the reference device communicates to the system.

The examiner takes official notice that wired and wireless connections are well known and that it would have been obvious to have the receiver integral with the system.

Claims 12, 14, 31-33, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrototaro in view of Sato et al 20030023171. Mastrototaro teaches that calibration is of sufficient quality when the correlation coefficient is .79 or greater. It does not teach how to measure the coefficient. Sato et al teaches in paragraph [0094] that least squares regression is a known method to calculate the correlation coefficient. As such, it would have been obvious to modify Mastrototaro to use a least squares regression to determine the correlation coefficient, as it is merely the substitution of one known determining method for another.

Claims 58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin et al 2002/0161288 in view of the Mastrototaro article. Shin teaches a matched pair calibration scheme similar to applicants which can calibrate once a day and can calibrate with one data point (see paragraph [0069]). Therefore, it is the examiner's position that once a day calibration using one matched pair is contemplated by Shin et al. It does not evaluate the quality of calibration using a data association function. However, as discussed above, Mastrototaro does, to ensure the accuracy of the readings. Hence, it would have been obvious to modify Shin et al to evaluate the calibration quality, to ensure the readings are accurate. With respect to claims 63 and 64, the data association function of Mastrototaro uses statistical analysis which is a form of evaluating the clinical acceptability of the data. Claims 65 and 66 are rejected in that

Shin further teaches calibrating the device during and after initialization to provide a forward looking calibration, and hence real time data. Claims 68 and 69 are rejected in that the examiner takes official notice that it is well known to smooth data, to eliminate the effects of anomalous data. As such, it would have been obvious to modify Shin et al to smooth the data, to improve the accuracy of measurements. Claims 71 and 72 are rejected in that the sensor is continuous and provides a graphical display. Claims 83-92 are rejected for the reasons given above.

Claims 62, 101, 102, and 106-110 are rejected under 35 U.S.C. 102(b) as being anticipated by the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System," which was cited by applicant in view of Causey III et al 6558320. In addition to the features of Mastrototaro discussed above, Mastrototaro provides retrospective calibration. Causey III et al teaches the equivalence of retrospective and real time calibration. Hence, it would have been obvious to modify Mastrototaro to provide real time data, as it is merely the substitution of one known calibration technique for another.

Claims 75-77, and 93-95 are rejected under 35 U.S.C. 102(b) as being anticipated by the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System," which was cited by applicant in view of Shin et al 2002/0161288. Shin further teaches calibrating the device during and after initialization to provide a forward looking calibration, and hence real time data. Hence, it would have been obvious to modify Mastrototaro to use such a calibration scheme, to improve the functionality of the device. In addition, Shin further teaches performing calibration every

Art Unit: 3735

time a matched pair is obtained (i.e. on a single matched pair) (see paragraph [0069]. Hence, it would have been obvious to modify Mastrototaro to perform calibration every time a pair is obtained, to improve the accuracy of calibration.

Claims 103-105 are rejected under 35 U.S.C. 102(b) as being anticipated by the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System," which was cited by applicant in view of Causey III, as applied to claims 62, 101, 102, and 106-110 above, further in view of Shin et al 2002/0161288. Shin further teaches calibrating the device during and after initialization to provide a forward looking calibration, and hence real time data. Hence, it would have been obvious to modify Mastrototaro to use such a calibration scheme, to improve the functionality of the device. In addition, Shin further teaches performing calibration every time a matched pair is obtained (i.e. on a single matched pair) (see paragraph [0069]. Hence, it would have been obvious to modify Mastrototaro to perform calibration every time a pair is obtained, to improve the accuracy of calibration.

Applicant's arguments filed 5/10/2007 have been fully considered but they are not persuasive.

Applicant has asserted that Mastrototaro provides data if the calibration exceeds a threshold, not the data association. The examiner disagrees, noting that Mastrototaro evaluates the correlation or mean absolute difference, which are data associations.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3735

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735



RLN
July 23, 2007